

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: DANNENMAIER, Jürgen)	Confirmation No. 2773
)	
Serial No.: 10/708774)	Group Art Unit: 1723
)	
Filed: 24-Mar-2004)	Examiner: MENON, Krishnan S.
)	
For: Filter Device Having More than One Filtration))	
Compartment)	
)	
<u>Customer No: 24994</u>)	

Mail Stop - Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

AMENDED APPEAL BRIEF UNDER 37 C.F.R 41.37

Pursuant to 37 C.F.R §41.37, Appellants submit this Amended Appeal Brief to the Board of Patent Appeals and Interferences in reply to the Notification of Non-Compliant Appeal Brief dated June 14, 2007. The original Appeal Brief, filed September 23, 2005, was held defective for not complying with 37 C.F.R. §41.37(c)(1)(iii) and 37 C.F.R. §41.37(c)(1)(v). The brief did not indicate the claims that are on appeal; and also did not identify and map independent claims 1 and 36 that are on appeal to specification by page and line number or paragraph number and/or drawings, if any.

I. Real Party in Interest

The real party in interest is Gambro Lundia AB, the assignee of the entire right, title and interest in the application at issue.

II. Related Appeals and Interferences

There are currently no related appeals or interferences pending before the Board of Patent Appeals and Interferences.

III. Status of Claims

Claims 1-43 are pending in the application. Claims 7-9, 13, 17, 18, 25-35, 37 and 40-43 have been withdrawn from consideration. Claims 1-6, 10-12, 14-16, 19-24, 36, 38 and 39 stand rejected.

Therefore, Claims 1-6, 10-12, 14-16, 19-24, 36, 38 and 39 are the subject of this appeal and are set forth in the attached Claims Appendix.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

The present invention relates to a filter device for the filtration of fluids. In particular, one or more embodiments of the present invention relate to filter devices for use in dialysis-type treatments and for filtration processes similar to and related to the haemodialysis process, such as haemofiltration, haemodiafiltration and ultrafiltration, as well as to a method for making a housing of a filtration device. The subject matter related to the method of making has been withdrawn from consideration in this application and is not the subject of this appeal. (Specification, Paragraph 2)

The filter device has at least two fluid filtration compartments are provided within a filter housing, the respective compartments being separated by an internal wall. A first surface of the filter membrane means is in communication with both an inlet and an outlet. (Specification, Paragraph 18) The housing comprises at least two longitudinally extending shell portions, one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of said housing comprises continuous internal walls, which divide the filter into separate filtration compartments. No single compartment would thereby be delimited entirely by peripheral or external walls of the housing, each compartment being delimited at least partly by an internal wall. The respective portions of the housing are joined together along seam-type joints by any suitable means such as by bonding or welding, for example, using ultrasound or laser welding. In the case of laser-welding techniques, the two sections of the filter housing would benefit from particular light reflective properties in order to ensure an adequate weld. For example, one of the housing sections may be made from substantially clear, uncolored material, while the other may contain a light-reflective dye suitable for causing plastics material at the boundary of the two housing portions to melt sufficiently to form a bond. In a possible embodiment of a laser-welded housing, one housing portion may be made from polycarbonate while another section may be made from polypropylene. (Specification, Paragraph 29)

Assembly of the filter device may be achieved by combining the steps of filling the respective filtration compartments as initially defined by the separate sections with hollow-fibers and then assembling the housing. For example, hollow-fibers may be placed within the

respective filtration compartments defined by each respective single section of the housing. The housing sections may then be brought together and fixed in position enclosing the respective fiber bundles in their compartments. The housing which is here, by way of example, shown tubular sections may thereby each include corresponding portions of internal walls, whereby the respective edges of the various corresponding wall portions would then desirably be bonded to one another as would the outer walls of the said sections. Bonding may be carried out by any suitable method such as by using adhesive means or by welding as described more fully herein. (Specification, Paragraph 30) The structure that enables this assembly is the subject matter of this appeal. Claims to the method of manufacture have been withdrawn from consideration. There are no "product by process" claims pending in this case. (Claims 1-3, 6, 10-12, and 14)

The claimed invention comprises [independent claim 1] a filter device having a housing 1 (§ 59), the housing enclosing at least two fluid filtration compartments 2 and 3 (Fig. 2, Fig. 3, § 59), each filtration compartment comprising at least one filter membrane (§ 59) having a first surface and a second surface, the first surface of each filter membrane being in fluid communication with at least one fluid flow port, the second surface being in fluid communication with at least one fluid flow port, adjacent filtration compartments being separated from each other by an internal wall 8 (§ 59), the housing comprising at least two longitudinally extending shell portions 41, 42 (Fig. 4, Fig. 5, § 65), one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of the housing (§ 65). [Dependent claim 2] One of the longitudinally extending shell portions may describe less than one third of the perimeter of the housing. (§ 31) [Dependant claim 6] The longitudinally extending shell portions may joined together along at least two longitudinal seams 35. (§ 42, § 65.)

In some embodiments, [dependant claim 10] the internal wall comprises a first part 48 and a second part 49 (§ 65), the first part being attached to a first longitudinally extending shell portion and the second part being attached to a second longitudinally extending shell portion, the first part having a free edge and the second part having a free edge, the free edges being configured to join to each other. (Figures 4, 5, 10, 11, 11a, 12, 13, 13a.) [Dependant claim 11] Each longitudinally extending shell portions may have two longitudinal edges, the longitudinal

edges of adjacent shell portions being configured to join to each other, and the free edge of a wall part attached to a shell portion may be non-coplanar with the longitudinal edges of the shell portion. (Figures 4, 5, 10, 11, 11a, 12, 13, 13a.) [Dependant claim 12] A larger one of the longitudinally extending shell portions of the housing may describe more than one half of the perimeter of the housing and the free edge of said wall part attached to the larger shell portion may extend beyond a plane containing said longitudinal edges of said larger shell portion. (Figures 4, 5, 10, 11, 11a, 12, 13, 13a.)

[Dependant claim 14, independent claim 36] One of the longitudinally extending shell portions may have a first refractive index and another of the longitudinally extending shell portions may have a second refractive index, the first refractive index being different from the second refractive index. (¶ 74.)

VI. Grounds of Rejection To Be Reviewed On Appeal

Claims 1, 4-6, 10-12 and 16 are rejected as anticipated by Gross et al. (US 5,882,516). In the alternative, the Examiner considered claims 6 and 10-12 obvious over the same reference. The Examiner also mentions, in this regard, claims 19-21 and 22-24. Claims 14, 15, 36, 38 and 39 are rejected under 35 USC § 103 over Gross in view of Pope et al. (US 2003/0102264).

VII. Argument

Gross shows a dialyzer having two modules or chambers, but as far as can be determined from the disclosure the elongated tubular housing 12 is comprised of a single piece. A separating wall 18 divides the housing into two modules. Significantly, the modules are delimited by the separating wall and the outer wall (singular) of the housing. See column 2, lines 61-67. There is no suggestion that the housing (exclusive of the wall) is formed of two parts.

VII. A. Claim 1

Claim 1 specifies that the housing comprises "at least two longitudinally extending shell portions, one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of said housing". This structure is not shown or suggested in Gross, even though the two modules are of different sizes. In Gross, the fiber filters would be inserted from an end of the tubular housing, not laid into one of the elongated longitudinally extending shell portions as would be possible in the claimed invention. The Examiner concedes that Gross does not expressly state the limitation. (Final Rejection, page 6, lines 3-4) The fact that a claimed structural feature will make it easier to manufacture a device is not proper grounds for rejection of the novel, unobvious structure. There is no such doctrine as a "reverse product-by-process claim", wherein an otherwise patentable structure, not shown in the prior art, may be rejected because the structure provides manufacturing advantages. The examiner states that "limitations that would make the method of manufacture easier is not patentable in the product claim." For this proposition, the examiner relies on *In re Thorpe* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). It is apparent from reading these claims that the process is not being claimed, nor is the product being claimed in terms of the process by which the product is made. Such claims are most frequently used in connection with chemical cases where the structure itself may not be known. In this case, the claims recite well-defined structural differences over the prior art. The principle advantage of this structure is found in connection with the manufacture of the product, but that fact does not convert the claim into a product-by-process claim. Indeed, although the assembly of the claimed invention may be easier than the prior art devices in that the fibers may be laid in one of the halves of the device, it is also more difficult in

that an appropriate seal between the two parts must be achieved for fluid integrity. Thus one of ordinary skill in the art would not find it obvious that such a structure would be appropriate or operable.

VII. B. Claim 6

Moreover, contrary to the examiner's assertion, claims 6, and 10-12 each recite further structural details not shown or suggested in Gross. Although these features may make the assembly of the dialyzer more effective than that of the prior art, they are nevertheless patentable. The examiner has misapplied the rule of *In Re Thorpe*, 777 F.2d 696, 227 USPQ 964 (Fed. Cir. 1985). The structure defined in claims 1, 6, and 10 through 12 is different from the prior art. The claims are not product-by-process claims. The examiner seems to be asserting that there must be a claimed difference in the functioning of the dialyzers described in Gross and in this application before a claim is allowable. Such a rule is not supported by the cited case or by statute. There is no statutory basis for the rejection of these claims. The examiner has failed to make a prima facie case for rejection of the claims. Claim 6 calls for two longitudinal seams where the two shells are joined. The prior art does not show two shells or any kind of seams

VII. C. Claim 10

The cited art does not show "internal wall [comprising] a first part and a second part, said first part being attached to a first longitudinally extending shell portion and said second part being attached to a second longitudinally extending shell portion, said first part having a free edge and said second part having a free edge, said free edges being configured to join to each other." (Claim 10) Except as described in the specification of this application, there is no suggestion in the art that the internal wall should comprise two parts. In fact, the potential difficulty of forming a seal along the internal wall would render the claimed structure less obvious, not more.

VII. D. Claim 11

Nor does Gross show or suggest that "each longitudinally extending shell portions has two longitudinal edges, the longitudinal edges of adjacent shell portions being configured to join to each other, and wherein the free edge of a wall part attached to a shell portion is not co-planar

with the longitudinal edges of said shell portion." (Claim 11.) (See Figs. 4 and 5 near numeral 48. See also Figs. 11, 11a, 12, 13, and 13a) This claimed feature helps one overcome the challenge presented to obtaining a seal along the internal walls. Since the prior art only teaches integral (one-piece) internal walls, the prior art does not address either the advantages or disadvantages of the claimed structure.

VII. E. Claim 12

Finally, Gross does not teach or suggest that "a larger one of said longitudinally extending shell portions of the housing describes more than one half of the perimeter of said housing and wherein said free edge of said wall part attached to said larger shell portion extends beyond a plane containing said longitudinal edges of said larger shell portion." (Claim 12) This structure allows the fibers to be laid into one portion of the shell while providing an elevated part of the internal wall of sealing. In the standard structure, fibers are inserted from an end of a unitary shell. The claimed structure further resolves the advantages and disadvantages inherent in the claimed two-part structure. Since the prior art address neither the disadvantages nor the advantages of the two part shells, the claimed structure cannot be either anticipated or obvious in view of art showing only a one-part shell.

The fact that a claimed structural feature will make it easier to manufacture a device is not proper grounds for rejection of the novel, unobvious structure. There is no such doctrine as a "reverse product-by-process claim", wherein an otherwise patentable structure, not shown in the prior art, may be rejected because the structure provides manufacturing advantages. Each of these claims should be allowed.

Claims 4, 5, 16, and 19-24 are allowable with their parent claims.

Response to Claims Rejections under 35 USC § 103

VII. F. Claim 2

The examiner acknowledges that the limitations of claims 2 and 3 are not specifically taught by Gross. Claim 2 is representative. Claim 2 specifies that one shell portion describes

less than one third of the perimeter of the housing. It is impossible to derive these limitations by "optimization" because, as pointed out above in connection with claim 1, these limitations refer to the separate shell portions, not to the modules or chambers that hold the filters. In the preferred embodiment, for instance, (e.g., Fig. 4 or Fig. 5), each shell portion forms part of both modules or chambers. This is not an express requirement of these claims, but it demonstrates that the examiner's argument that the size of the filter would lead one to the claims by mere optimization is simply wrong. Clearly, under the structure claimed in claim 1, the chambers could be of different size, because of the placement of the internal wall, but the shell portions could nevertheless be identical mirror images of each other. The placement of the inner wall could accommodate any size of filter in either chamber, regardless of the proportions of the two shells. There would, therefore, be no motivation to "optimize" the shells based on the size of the filters, as suggested by the examiner. Rather, the structure of claim 2 (and 3) may aide in placing both filters into the larger shell before the second, smaller shell is sealed onto the larger shell. This structure, however, is not suggested nor optimized from the structure of Gross because the apparatus of Gross is assembled in a different way. Claim 2 (and Claim 3) is allowable over the art.

VII. G. Claim 14

The examiner has rejected claims 14, 15, 36, 38 and 39 under 35 USC § 103 over Gross in view of Pope et al. (US 2003/0102264). Claim 14 is representative of these claims. Pope et al. does disclose the use of polycarbonate and polypropylene in the end caps and the tubular housing of a dialyzer, but neither Pope nor Gross disclose or suggest the two longitudinally extending shell portions claimed herein. Pope cannot, therefore teach that the two shell portions should have different optical properties or refractive indices. It should be noted that "adhesive" is not a limitation of any of the claims, although that is a method for assembling the shells that would not require different optical properties to be effective. The claims presented must be considered on their merits and not by the incorporation of an "adhesive" limitation not contained in the claims. The specification teaches that different optical properties for two longitudinally extending halves may be useful in providing a secure seal between the halves. Since the prior art does not teach the use of two halves joined in any way, it cannot be obvious to provide halves

having different physical characteristics. Claim 14 should be allowed. Claims 15, 36, 38 and 39 should have been allowed for similar reasons.

For at least the reasons given above, the Board of Patent Appeals and Interferences should reverse the claim rejections under 35 USC §102(e) and 103(a) and permit allowance of claims 1- 6, 10-12, 14-16, 19-24, 36, 38 and 39.

Respectfully submitted,

July 11, 2007
Date


John R. Merkling (Reg. No: 31716)
Gambro BCT, Inc.
10810 W. Collins Ave.
Lakewood, Colorado 80215 U.S.A.
Tel. (303) 239-2362

VIII. Claims Appendix

1. (Original) A filter device comprising a housing, said housing enclosing at least two fluid filtration compartments, each filtration compartment comprising at least one filter membrane having a first surface and a second surface, said first surface of each filter membrane being in fluid communication with at least one fluid flow port, said second surface being in fluid communication with at least one fluid flow port, adjacent filtration compartments being separated from each other by an internal wall, said housing comprising at least two longitudinally extending shell portions, one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of said housing.
2. (Original) The filter device of Claim 1 wherein the one of said longitudinally extending shell portions describes less than one third of the perimeter of said housing.
3. (Original) The filter device of Claim 2 wherein the one of said longitudinally extending shell portions describes less than one quarter of the perimeter of said housing.
4. (Original) The filter device of Claim 1 wherein said housing is tubular.
5. (Original) The filter device of Claim 4 wherein said perimeter of said housing is a circumference.
6. (Currently Amended) The filter device of claim 1 wherein said longitudinally extending shell portions are joined together along at least two longitudinal seams.
7. (Withdrawn) The filter device of Claim 1, wherein at least one filtration compartment comprises at least two spaced apart generally planar walls and said walls are in a parallel relationship to each other.

8. (Withdrawn) The filter device of Claim 7 wherein each filtration compartment comprises at least two spaced apart generally parallel walls and said walls are in a parallel relationship with each other.

9. (Withdrawn) The filter device of Claim 8 wherein said filter device comprises three filtration compartments.

10. (Original) The filter device of Claim 1, wherein said internal wall comprises a first part and a second part, said first part being attached to a first longitudinally extending shell portion and said second part being attached to a second longitudinally extending shell portion, said first part having a free edge and said second part having a free edge, said free edges being configured to join to each other.

11. (Original) The filter device of Claim 10, wherein each longitudinally extending shell portions has two longitudinal edges, the longitudinal edges of adjacent shell portions being configured to join to each other, and wherein the free edge of a wall part attached to a shell portion is not co-planar with the longitudinal edges of said shell portion.

12. (Original) The filter device of claim 11 wherein a larger one of said longitudinally extending shell portions of the housing describes more than one half of the perimeter of said housing and wherein said free edge of said wall part attached to said larger shell portion extends beyond a plane containing said longitudinal edges of said larger shell portion.

13. (Withdrawn) The filter device of Claim 1 wherein one of said longitudinally extending shell portions comprises a substantially clear, uncoloured material at at least a boundary thereof and wherein another of said longitudinally extending shell portions comprises a coloured material at at least a boundary of said another shell portion, whereby a laser or electromagnetic radiation weld may be formed between the boundaries of said shell portions.

14. (Original) The filter device of Claim 1 wherein one of said longitudinally extending shell portions has a first refractive index and another of said longitudinally extending shell portions

has a second refractive index, said first refractive index being different from said second refractive index.

15. (Original) The filter device of Claim 14 wherein said one of said longitudinally extending shell portions is comprised of polycarbonate and said another of said longitudinally extending shell portions is comprised of polypropylene.

16. (Original) The filter device of Claim 1, comprising two filtration compartments arranged within said housing and wherein one of said filtration compartments is suitable for carrying out ultrafiltration of a first fluid while the other compartment is suitable for simultaneously carrying out either haemofiltration or haemodialysis or haemodiafiltration of a second fluid.

17. (Withdrawn) The filter device of claim 1, wherein said device comprises a housing within which are arranged at least three filtration compartments and wherein at least one of said filtration compartments is suitable for carrying out ultrafiltration of a first fluid while each of the other compartments is suitable for simultaneously carrying out either haemofiltration or haemodialysis or haemodiafiltration of a second fluid.

18. (Withdrawn) The filter device of Claim 17, wherein said first surfaces of at least two of said filter membranes in separate filtration compartments are in fluid flow communication.

19. (Original) The filter device of Claim 1, wherein said second surfaces of said filter membrane of one of said filtration compartments are in fluid communication with said first surface of said filter membrane in another of said filtration compartments.

20. (Original) The filter device of Claim 19, wherein said first surface of said filter membrane of one said filtration compartments is in fluid communication with said second surfaces of said filter membrane in another of said filtration compartments via an external fluid flow port.

21. (Original) The filter device of Claim 1, wherein said filter membrane comprises a bundle of semi-permeable hollow-fibre membranes and wherein said first surface is comprised of the interior surfaces of said hollow-fibres in said bundle and wherein said second surface is comprised of the exterior surfaces of said hollow-fibres in said bundle.

22. (Original) The filter device of Claim 21, wherein said housing comprises two opposed ends and a tubular external wall therebetween, said hollow-fibre membranes being arranged within each of said filtration compartments along the longitudinal direction of said tubular housing, wherein the ends of said hollow fibre membranes are secured by and embedded within a potting compound.

23. (Original) The filter device of Claim 22, wherein an end-cap is fixed to each end of the tubular housing and wherein a header chamber is provided between each said end-cap and the ends of said hollow fibres.

24. (Original) The filter device of Claim 23, wherein said external wall of said tubular housing is provided at its ends with engagement portions for positively engaging said potting compound.

25. (Withdrawn) The filter device of claim 1, wherein said longitudinally extending shell portions are welded together.

26. (Withdrawn) The filter device of claim 25, wherein said longitudinally extending shell portions are laser welded.

27. (Withdrawn) The filter device of claim 25, wherein said longitudinally extending shell portions are ultrasound welded.

28. (Withdrawn) A filter device comprising a housing, said housing enclosing at least two fluid filtration compartments, each filtration compartment comprising at least one filter membrane having a first surface and a second surface, said first surface of each filter membrane

being in fluid communication with at least one fluid flow port, said second surface being in fluid communication with at least one fluid flow port, adjacent filtration compartments being separated from each other by an internal wall, said housing comprising at least two longitudinally extending shell portions, wherein at least one filtration compartment comprises at least two spaced apart generally planar walls and said walls are in a parallel relationship to each other.

29. (Withdrawn) The filter device of Claim 28 wherein each filtration compartment comprises at least two spaced apart generally parallel walls and said walls are in a parallel relationship with each other.

30. (Withdrawn) The filter device of Claim 29 wherein said filter device comprises three filtration compartments.

31. (Withdrawn) A method of making a filter device comprising the steps of
forming a housing for enclosing at least two fluid filtration compartments, said housing comprising at least two longitudinally extending shell portions, one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of said housing, adjacent filtration compartments being separated from each other by an internal wall,
placing at least one filter membrane having a first surface and a second surface longitudinally in each filtration compartment;
closing said shell portions around said filter membranes to form said fluid filtration compartments;
sealing adjacent edges of said shell portions;
imbedding ends of said filter membranes in a potting compound; and
capping the ends of said housing.

32. (Withdrawn) The method of Claim 31, further comprising providing at least two spaced apart generally planar walls in each fluid filtration compartment, said walls being in a parallel relationship to each other and packing a plurality of filter membranes between said walls.

33. (Withdrawn) The method of Claim 32, further comprising
forming one of said longitudinally extending shell portions from a substantially clear, uncoloured material at at least a boundary thereof,
forming another of said longitudinally extending shell portions of a coloured material at at least a boundary of said another shell portion, and
wherein said step of sealing adjacent edges comprises differential heating of said colored material and said uncoloured material by laser or electromagnetic radiation.

34. (Withdrawn) The method of Claim 32, further comprising
forming one of said longitudinally extending shell portions from a first material having a first refractive index and
forming another of said longitudinally extending shell portions from a second material having a second refractive index, said first refractive index being different from said second refractive index, and
wherein said step of sealing adjacent edges comprises differential heating of said first material and said second material by laser or electromagnetic radiation.

35. (Withdrawn) The method of Claim 34 comprising
forming said one of said longitudinally extending shell portions from polycarbonate, and
forming said another of said longitudinally extending shell portions from polypropylene.

36. (Original) A filter device comprising
a housing, said housing having
at least two longitudinally extending shell portions
one of said longitudinally extending shell portions having a first optical property
and
another of said shell portions having a second optical property, said first optical property being different from said second optical property,
at least one filter membrane disposed within said housing and extending longitudinally from a first end to a second end of said housing,
end caps closing said ends of said housing, and

at least one access port for introducing fluid into or out of said filter device.

37. (Withdrawn) The filter device of claim 36 wherein said optical property is colour.

38. (Original) The filter device of claim 36 wherein said optical property is a refractive index.

39. (Original) The filter device of Claim 38 wherein said one of said longitudinally extending shell portions is comprised of polycarbonate and said another of said longitudinally extending shell portions is comprised of polypropylene.

40. (Withdrawn) The filter device of claim 36, wherein said longitudinally extending shell portions are welded together.

41. (Withdrawn) The filter device of claim 40, wherein said longitudinally extending shell portions are laser welded.

42. (Withdrawn) The filter device of claim 40, wherein said longitudinally extending shell portions are ultrasound welded.

43. (Withdrawn) The filter device of claim 36 wherein said housing further comprises an internal wall, said wall separating said housing into first and second compartments, said wall having

a first wall portion extending from said one of said longitudinally extending shell portions and having said first refractive index and
a second wall portion extending from said another of said longitudinally extending shell portions and having said second refractive index, said first wall portion being welded to said second wall portion.

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None